

REMARKS

In the Office Action, claims 1-5 and 7-40 were rejected. Reconsideration and allowance of all pending claims are requested.

Rejections Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 1-5 and 7-40 as obvious in view of various combinations and permutations of Kieffer, a first Yabe et al. reference (U.S. Patent No. 5,458,133; hereinafter “Yabe ‘133”), a second Yabe et al. reference (U.S. Patent No. 5,514,074; hereinafter “Yabe ‘074”), and Moriyama (U.S. Patent App. Pub. No. 2002/0013510; hereinafter “Moriyama”). Applicants address each of these rejections in turn below.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated

disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Kieffer Does Not Disclose a Cover Disposed on an Otoscope When the Otoscope is Not in Use.

Turning now to the claims, independent claims 1, 8, 15, 22, 27, 31 and 36 recite a body, or cover, or means or first and second cover members configured to releasably secure to a probe end of an endoscope such that the aforementioned elements are configured to be *disposed on the tip of the endoscope only when the endoscope is not in use*. Thus, Applicants stress that the above mentioned cover members are uniquely designed to be disposed on the tip of an endoscope. Moreover, the claimed covers are specifically configured to promote the sterile condition of the endoscope by being disposed on the tip of the endoscope *only when the endoscope is not in use*.

In contrast, Kieffer discloses a device specifically designed to be used with an otoscope. Specifically, Kieffer teaches a removable speculum which contains a “rubber-like tip bounded upon the distal end thereof for protecting the ear canal and forming a seal therewith.” *See*, Kieffer, Abstract and Fig. 1. Thus, the otoscope cover taught by Kieffer would *only* be used during examinations, as it is intended to facilitate use of the otoscope *and* to promote patient comfort. As one of ordinary skill in the art would appreciate, the speculum taught by Kieffer is not configured to be disposed on the tip of the otoscope only when the otoscope is not in use, as recited by the claims.

Further, in Response to Arguments, the Examiner asserted that “Kieffer *clearly shows* a cover 41 (the removable speculum) for use with an endoscope 20 (see Fig. 2).” *See*, Final Office Action, page 6 (Emphasis added). Applicants respectfully submit that in contrast to the Examiner’s assertion, there are no disclosures or suggestions in Kieffer pointing to a cover, i.e., speculum, used with an endoscope. Applicants challenge the Examiner to show where in Kieffer it is disclosed or suggested that the cover 41 is used

with endoscope. In fact, there is not a single occurrence of the word “endoscope” in Kieffer.

The Examiner further asserted in Response to Arguments that:

a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentable distinguish the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Final Office Action, page 6.

Applicants submit that there is a stark structural distinction between an endoscope and an otoscope, rendering a clear structural distinction, as well, between the claimed endoscope cover and the speculum taught by Kieffer. The speculum taught by Kieffer is incapable of performing the intended use of the claimed endoscope cover. Therefore, in parallel with the reasoning provided above by the Examiner, because the structure disclosed by the prior art is incapable of performing the intended use then the prior art does not meet the claim.

Moreover, it is unlikely that a speculum specifically configured to be disposed on an otoscope could be securely fitted on a probe end of an endoscope. As mentioned above, these two devices are inherently different both in their structure and functionality. In so stating, Applicants wish to reassert, as stated in previous Responses, that the subject matter disclosed by Kieffer is non-analogous art. Accordingly, Applicants submit that the prior art used in this case is not within the field of the inventors’ endeavor. Specifically, Kieffer teaches a device apparently meant to aid clinicians specializing in medicine related to an anatomical part, such as an ear, a nose and/or a throat. In contrast, the Applicants’ endeavor is in a field of medicine related to internal anatomical cavities, some of which may include internal organs and tissues. This is the clear field of use of an

endoscope. The mere fact that the device claimed in the present patent application and the one disclosed in Kieffer are both used in the general field of medicine is insufficient to regard them as in the same field.

Further, Applicants submit that Kieffer is not reasonably pertinent to the particular problem with which the inventors are involved. The speculum taught by the cited reference is meant to protect the ear canal as it is probed. The endoscope cover presently claimed is meant to protect *an endoscope while it is not in use* and, in so doing, it properly maintains the sterile condition of the endoscope when it is not in use. Indeed, the claimed endoscope cover would never be used while the endoscope is in use. These are two very distinct problems. As one having ordinary skill in the art would appreciate, a design of a cover for an apparatus used in a medical procedure, where the cover may contact delicate organs of a human body during a procedure (as in Kieffer), is clearly distinct from a design of a cover configured to protect an apparatus, such as an endoscope, while not in use. Accordingly, Kieffer is not reasonably pertinent to the particular problem with which the inventors are involved. Accordingly, Applicants submit, here again, that subject matter taught by the Kieffer reference is non-analogous art.

Yabe '074 and Yabe '133 Do Not Disclose a Cover Disposed on an Endoscope When the Endoscope is Not in Use.

In rejecting the claims the Examiner combined the teachings of Kieffer with those of Yabe '074 and/or Yabe '133 to render the claims obvious. However, Applicants contend that Yabe '074 and Yabe '0133, like Kieffer, teach an endoscope cover disposed on a probe end of an endoscope while the endoscope is in use. That is, these references teach a cover disposed on an instrument insertable into a body of a patient. For example, Yabe '074 teaches “*insert* part covering section 11A is taken out of the storage package of the cover (not illustrated) containing the antibacterial endoscope cover 2A.” Yabe '074, col. 12, lines 4-6. Further Yabe '074 discloses “the insert part cover section 11A

including the insert part 11B is inserted into the patient's body." Yabe '074, col. 12, 20-22; *see also* Figs. 1 and 8. Accordingly, Yabe '074 does not teach or suggest a cover configured to be disposed on the tip of a probe end of an endoscope only when the endoscope is not in use, as recited by the claims.

Similarly, Yabe '133 discloses "an endoscope examination is carried out by using a cover type endoscope apparatus." Yabe, col. 4, lines 52-53; *see also* Figs. 1 and 2. Hence, the cover taught by Yabe '133 is used while the endoscope is in use, i.e., the cover may be inserted into the body. In view of this, Yabe '133 clearly does not disclose or suggest a cover configured to be disposed on the tip of a probe end of an endoscope only when the endoscope is not in use, as recited by the claims.

Consequently, the combination of Kieffer and Yabe '074 and/or with Yabe '133 clearly does not and cannot establish a *prima facie* case of obviousness of claims 1, 8, 15, 22, 27, 31 and 36. Accordingly, Applicants request the Examiner to remove the rejections and allow independent claims 1, 8, 15, 22, 27, 31 and 36 and claims dependent therefrom.

Claims 19-21 and 37-40 are Allowable.

In the Office Action, dependent claims 19-21 and 37-40 were rejected under Section 103 as obvious in view of various reference combinations. Applicants, however, respectfully submit that these claims, which depend from the independent claims discussed above, are patentable by virtue of their respective dependencies from allowable based claims, and also by virtue of the additional features recited therein. Therefore, Applicants respectfully request reconsideration and allowance of these claims.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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